# PATENT COOPERATION TREATY

From the
INTERNATIONAL SEARCHING AUTHORITY

To:

see form PCT/ISA/220

# PCT

## WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY

(PCT Rule 43*bis*.1)

Date of mailing
*(day/month/year)* see form PCT/ISA/210 (second sheet)

Applicant's or agent's file reference
see form PCT/ISA/220

**FOR FURTHER ACTION**
See paragraph 2 below

| International application No. | International filing date *(day/month/year)* | Priority date *(day/month/year)* |
|---|---|---|
| PCT/US2004/043585 | 29.12.2004 | 31.12.2003 |

International Patent Classification (IPC) or both national classification and IPC
G01N21/53, B01L3/00, G01N33/58

Applicant
PRESIDENT AND FELLOWS OF HAWARD COLLEGE

1. This opinion contains indications relating to the following items:

- ☒ Box No. I Basis of the opinion
- ☒ Box No. II Priority
- ☐ Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- ☐ Box No. IV Lack of unity of invention
- ☒ Box No. V Reasoned statement under Rule 43*bis*.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- ☐ Box No. VI Certain documents cited
- ☒ Box No. VII Certain defects in the international application
- ☒ Box No. VIII Certain observations on the international application

2. **FURTHER ACTION**

If a demand for international preliminary examination is made, this opinion will usually be considered to be a written opinion of the International Preliminary Examining Authority ("IPEA"). However, this does not apply where the applicant chooses an Authority other than this one to be the IPEA and the chosen IPEA has notifed the International Bureau under Rule 66.1*bis*(b) that written opinions of this International Searching Authority will not be so considered.

If this opinion is, as provided above, considered to be a written opinion of the IPEA, the applicant is invited to submit to the IPEA a written reply together, where appropriate, with amendments, before the expiration of three months from the date of mailing of Form PCT/ISA/220 or before the expiration of 22 months from the priority date, whichever expires later.

For further options, see Form PCT/ISA/220.

3. For further details, see notes to Form PCT/ISA/220.

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# WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY



## Box No. I Basis of the opinion

1. With regard to the **language**, this opinion has been established on the basis of the international application in the language in which it was filed, unless otherwise indicated under this item.

   ☐ This opinion has been established on the basis of a translation from the original language into the following language , which is the language of a translation furnished for the purposes of international search (under Rules 12.3 and 23.1(b)).

2. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application and necessary to the claimed invention, this opinion has been established on the basis of:

   a. type of material:

   ☐ a sequence listing

   ☐ table(s) related to the sequence listing

   b. format of material:

   ☐ in written format

   ☐ in computer readable form

   c. time of filing/furnishing:

   ☐ contained in the international application as filed.

   ☐ filed together with the international application in computer readable form.

   ☐ furnished subsequently to this Authority for the purposes of search.

3. ☐ In addition, in the case that more than one version or copy of a sequence listing and/or table relating thereto has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that in the application as filed or does not go beyond the application as filed, as appropriate, were furnished.

4. Additional comments:

## Box No. II Priority

1. ☒ The validity of the priority claim has not been considered because the International Searching Authority does not have in its possession a copy of the earlier application whose priority has been claimed or, where required, a translation of that earlier application. This opinion has nevertheless been established on the assumption that the relevant date (Rules 43*bis*.1 and 64.1) is the claimed priority date.

2. ☐ This opinion has been established as if no priority had been claimed due to the fact that the priority claim has been found invalid (Rules 43*bis*.1 and 64.1). Thus for the purposes of this opinion, the international filing date indicated above is considered to be the relevant date.

3. Additional observations, if necessary:

**Box No. V Reasoned statement under Rule 43*bis*.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement**

1. Statement

| | | | |
|---|---|---|---|
| Novelty (N) | Yes: | Claims | 1-25,32,33,37-42,48-50,52,53,56-71 |
| | No: | Claims | 26-31,34-36,43-47,51,54,55 |
| Inventive step (IS) | Yes: | Claims | |
| | No: | Claims | 1-71 |
| Industrial applicability (IA) | Yes: | Claims | 1-71 |
| | No: | Claims | |

2. Citations and explanations

**see separate sheet**

**Box No. VII Certain defects in the international application**

The following defects in the form or contents of the international application have been noted:

**see separate sheet**

**Box No. VIII Certain observations on the international application**

The following observations on the clarity of the claims, description, and drawings or on the question whether the claims are fully supported by the description, are made:

**see separate sheet**

**WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY (SEPARATE SHEET)**

International application No.
PCT/US2004/043585



Re Item V

**Reasoned statement with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement**

1. Reference is made to the following documents:

   D1: US 6,146,589 A
   D2: WO 91/01003 A
   D3: Sia S K and Whitesides G M, Electrophoresis, 24, 3563-3576, November 2003.

2. From what can be understood from the description, the present invention appears to be directed to performing the silver enhanced immunogold assay described, e.g., in WO 91/01003 (D2) cited in the description, in a microfluidics device. Thus, the following assessment of novelty and inventive step is restricted to independent claims 26 and 56 which comprise the largest number of technical features essential for the implementation of the invention.

2a. **Independent method claim 26**

D1 describes a method of detecting an analyte in a fluid sample, comprising (cf. col. 8, l. 9-38; fig. 1):

passing a fluid sample over a surface;
allowing the analyte to bind with a binding partner immobilized on the surface;
allowing a metal colloid to associate with the analyte; and
flowing a metal solution over the surface to form a metallic layer.

The method according to independent claim 26 is therefore not new (Article 33 (2) PCT).

2b. **Independent apparatus claim 56**

D1 discloses an immunoassay kit comprising (cf. col. 8, l. 9-38; fig. 1):

a surface including two channels (3,4);
an antibody (9) immobilized on a portion of the channel;

a metal colloid (8) associated with an antibody (6);
a metal precursor (10); and
instructions for performing the assay (implicit).

The assay kit according to claim 56 differs from the disclosure of D1 in that the channel is a microfluidic channel.

The technical problem may therefore be seen in miniaturizing the assay kit of D1.

The use of microfluidics is well-known in the art of immunoassays, see, e.g., D3, pages 3568-3569. The skilled person would therefore envisage using this technology when confronted with the above-mentioned technical problem.

The assay kit according to claim 56 is therefore considered to be fairly suggested by D1 in combination with D3 (Article 33 (3) PCT).

2c. The subject-matter of claims 1-25, 27-55, and 57-71 is not considered to be new and/or involve an inventive step, see documents D1-D3 and the corresponding passages cited in the International Search Report.

**Re Item VII**

**Certain defects in the international application**

1. Contrary to the requirements of Rule 5.1(a)(ii) PCT, the relevant background art disclosed in the documents D1 and D3 is not mentioned in the description, nor are these documents identified therein.

2. The independent claims are not in the two-part form in accordance with Rule 6.3(b) PCT, which in the present case would be appropriate, with those features known in combination from the prior art (document D1) being placed in the preamble (Rule 6.3(b)(I) PCT) and with the remaining features being included in the characterising part (Rule 6.3(b)(ii) PCT).

3. According to the requirements of Rule 11.13(l) reference signs not appearing in the description shall not appear in the drawings, and vice versa. This requirement is not met in view of the reference signs 230, 320, 330, and 340 used in figures 2 and 3, respectively.

## Re Item VIII

## Certain observations on the international application

Although claims 1, 26, 45, and 58 and claims 19 and 56 have been drafted as separate independent claims of category method and apparatus, respectively, they appear to relate effectively to the same subject-matter and to differ from each other only with regard to the definition of the subject-matter for which protection is sought. The aforementioned claims therefore lack conciseness and as such do not meet the requirements of Article 6 PCT.

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